IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

RAE SCHIFF,

Plaintiff,

12cv0264
ELECTRONICALLY FILED

v.

DENNIS J. HURWITZ, M.D., ET AL.,

Defendants.

Memorandum Opinion re: Defendant's Motion To Dismiss (Doc. No. 29)

I. Introduction

Presently before this Court is the Motion to Dismiss filed by defendant Essex Institutional Review Board (hereinafter "Essex"). This is an action sounding in medical negligence based upon a "BodyTite Procedure" that plaintiff underwent and was performed by co-defendant Dr. Dennis Hurwitz.[1] Co-defendant Invasix is the manufacturer of the medical device used in the "BodyTite Procedure" (hereinafter the "Invasix device"). After careful consideration of defendants' Motion to Dismiss (doc. no. 29) and Brief in Support (doc. no. 30), as well as plaintiff's Brief in Opposition (doc. no. 54), defendant's Motion to Dismiss (doc. no. 29) will be DENIED.

II. Factual Background

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, at this stage the Court accepts all of the factual allegations in the Complaint as true and all reasonable inferences are drawn in plaintiff's favor. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

[1] This Court has previously denied Dr. Hurwitz's Motion to Dismiss. Doc. No. 19. The Court has also granted in part and denied in part a Motion to Dismiss filed by Invasix. Doc. No. 44.

Taking plaintiff's factual allegations as true solely for the purposes of this Memorandum Opinion, the facts of this case are as follows:

Invasix allegedly failed to properly label the Invasix device and failed to get proper approval as required by the Code of Federal Regulations (CFR). *See generally* doc. no. 1, ¶ 155. Invasix was allegedly aware that the device was unsafe but failed to notify plaintiff of this fact. *Id*.

On April 23, 2009, during an initial consultation with Schiff, Dr. Hurwitz planned surgery in two stages—stage one would include a "tummy tuck" and stage two would include a lower body lift. *Id.*, ¶ 72. On December 1, 2009, Schiff spoke with Dr. Hurwitz about dividing the operations into smaller procedures; however, Dr. Hurwitz allegedly never discussed nor documented the potential risk of the device used to perform these procedures, the Radio-Frequency Assisted Lipolysis ("RFAL"). *Id.*, ¶ 74.

On March 2, 2010, Schiff was given pre-operative markings, and according to Dr. Hurwitz's chart, RFAL was discussed with Schiff but not the specific risks of the procedure. *Id.*, ¶ 76. On March 3, 2010, Dr. Hurwitz performed a "BodyTite Procedure"[2] on Schiff using the Invasix Device. *Id.*, ¶¶ 78-79. Prior to the surgery, plaintiff signed a form in which Invasix agreed to pay her a sum of $175 and any treatment of injury arising out of the Invasix device. *Id*. ¶¶ 188-89.

During the procedure, Dr. Hurwitz was serving as an investigator for the Invasix Device in a clinical trial sponsored by Invasix and approved by Essex Institutional Research Board. *Id.*, ¶ 80. Schiff was allegedly unaware that Dr. Hurwitz was a paid investigator for the Invasix Device, that the Invasix Device was being used in a clinical trial sponsored by Invasix, and that

[2] "BodyTite Procedure" refers to the numerous procedures Dr. Hurwitz performed on Schiff on March 3, 2010. See Doc. No. 1, ¶ 79(a) – (d).

the Food and Drug Administration ("FDA") neither was aware of nor approved of the clinical trial of the Invasix Device. *Id.*, ¶¶ 86-87.

Prior to the "BodyTite Procedure" on March 3, 2010, Dr. Hurwitz allegedly failed to disclose to Schiff that: (1) she was not a candidate for the procedure due to the clinical study's protocol; (2) the clinical study's protocols limited the Invasix Device from being used on more than three areas of the body; and (3) Schiff could be paid for her participation as a subject of the investigation of the "BodyTite Procedure." *Id.*, ¶¶ 88-90.

On March 9, 2010, approximately six days after surgery, Schiff complained of increased pain, swelling, and fever during her first post-op visit to Dr. Hurwitz's office. *Id.*, ¶ 91. Over the course of several subsequent days, Schiff had increased pain on all areas of her body in which the procedure was performed and began taking medication prescribed by Dr. Hurwitz. *Id.*, ¶ 93.

By Mid-April 2010, Schiff's pain was allegedly uncontrollable even with prescribed medication. *Id.*, ¶ 94. The procedures performed by Dr. Hurwitz left Schiff with irregular scars and scar tissue, and in August of 2010, she was diagnosed with having developed a thermal mediated demyelination of the sensory and autonomic nerves in the thighs leading to a diffuse post RFAL dysesthesia of the thighs and lymphatic system compromise. *Id.*, ¶¶ 95, 97. Schiff avers that her injuries were the direct and proximate result of negligence of each defendant. *Id.*, ¶ 98.

Essex allegedly approved the Clinical Trial Application from Invasix and its non-significant risk designation. *Id.*, ¶¶ 42, 54. This was meant to bypass FDA requirements. *Id.*, ¶ 44. This permitted Invasix to begin trials of the Invasix device. *Id.* Plaintiff avers that had the Invasix device been properly characterized, by either Invasix or Essex, as a Class II significant risk device, Invasix would have been required to secure either FDA premarket approval or an

Investigational Device Exemption order. *Id*., ¶¶ 24, 28. Essex was required to review and approve the research protocols, informed consent process, and the medical investigators involved in the clinical trial. *Id*., ¶¶ 48, 182.

III. Standard of Review

In considering a Motion to Dismiss brought pursuant to Fed.R.Civ.P. 12(b)(6), federal courts require notice pleading, as opposed to the heightened standard of fact pleading. Federal Rule of Civil Procedure 8(a)(2) requires only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds on which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Building upon the landmark United States Supreme Court decisions in *Twombly*, 550 U.S. 554 and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the United States Court of Appeals for the Third Circuit explained that a District Court must take three steps to determine the sufficiency of a Complaint:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Third, "whe[n] there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the Complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the Complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.

Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (quoting *Iqbal*, 556 U.S. at 662).

The third step of the sequential evaluation requires this Court to consider the specific nature of the claims presented and to determine whether the facts pled to substantiate the claims are sufficient to show a "plausible claim for relief." "While legal conclusions can provide the

framework of a Complaint, they must be supported by factual allegations." *Id.*; *See also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009).

The Court may not dismiss a Complaint merely because it appears unlikely or improbable that plaintiff can prove the facts alleged or will ultimately prevail on the merits. *Twombly*, 550 U.S. at 563 n.8. Instead, the Court must ask whether the facts alleged raise a reasonable expectation that discovery will reveal evidence of the necessary elements. *Id.* at 556. Generally speaking, a Complaint that provides adequate facts to establish "how, when, and where" will survive a Motion to Dismiss. *Fowler*, 578 F.3d at 212; *see also Guirguis v. Movers Specialty Services, Inc.*, 346 Fed. App'x. 774, 776 (3d Cir. 2009).

In short, the Motion to Dismiss should not be granted if a party alleges facts, which could, if established at trial, entitle him or her to relief. *Twombly*, 550 U.S. at 563 n.8.

IV. Discussion

A. Claims are Not Preempted by the Medical Devices Act

Defendant argues the negligence claims are preempted by the Medical Devices Act (MDA), 21 U.S.C. §360c *et seq*. The MDA preemption provision provides that:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel v. Medtronic Inc*., 552 U.S. 312, 321-23 (2008) the United States Supreme Court held that state law claims are preempted by the MDA if: (1) "specific requirements applicable to a particular device" have been established; and (2) the claims are based on "state

requirements" related to safety and effectiveness that are "different from, or in addition to" the federal requirements. *See also Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Gross v. Stryker Corp.*, -- F.Supp.2d --, 2012 WL 876719, at *11 (W.D. Pa. March 14, 2012) (Fischer, J). "State requirements" subject to federal preemption include common law causes of action, such as negligence, strict liability, and breach of implied warranty. *Riegel*, 552 U.S. at 324-25, 327-28; *see also Williams*, 388 F. App'x at 171 ; *Gross*, 2012 WL 876719 at *11.

The Court has already ruled on the preemption issue presented by defendant Essex in its Motion, and has previously held that the claims in this case were not preempted by the MDA. Doc. No. 43, 8-9. Defendant presents no authority, and the Court has not been able to locate any authority, for the proposition that a claim can be preempted against a review board but not against the device manufacturer. Thus, the Court adopts and incorporates by reference the analysis at doc. no. 43, 8-9, and holds that the MDA does not preempt the negligence claims against Essex.

B. Plaintiff Has Stated a Claim for Unfair Trade Practices and Negligence

Next, defendant argues that plaintiff has failed to state a claim for unfair trade practices under Pennsylvania law. *Inter alia*, Pennsylvania considers the following to be unfair trade practices:

> (a) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have.
>
> (b) Engaging in any other fraudulent or deceptive conduct which creates likelihood of confusion or of misunderstanding.

73 P.S. §201-2 (4)(v); 73 P.S. §201-2(4)(xxi). "Since the Consumer Protection Law was in relevant part designed to thwart fraud in the statutory sense, it is to be construed liberally to effect its object of preventing unfair or deceptive practices." *Commonwealth v. Monumental Properties, Inc.*, 329 A.2d 812, 817 (Pa. 1974). "Neither the intention to deceive nor actual

deception must be proved; rather, it need only be shown that the acts and practices are capable of being interpreted in a misleading way." *Commonwealth ex rel. Corbett v. Peoples Benefit Services, Inc*., 923 A.2d 1230, 1236 (Pa. Commw. 2007) (citing *Commonwealth ex rel. Zimmerman v. Nickel*, 26 Pa. D.& C.3d 115, 120 (1983)).

Plaintiff's Complaint contains more than conclusory allegations that Essex engaged in unfair trade practices. In Paragraph 183 of the Complaint, plaintiff alleges that Essex did not consider the significant risk of injury posed by the Invasix device, including the risk of permanent injury, when it accepted the non-significant risk designation. Doc. No. 1, ¶ 183. The Complaint further avers that Essex engaged in unfair trade practices because the FDA had not given prior approval for radio frequency devices in lipoplasty or other plastic surgery procedures. *Id*. These facts, in addition to others in the Complaint, are sufficient to state a claim for unfair trade practices and negligence.

C. Plaintiff Has Stated a Claim for Intentional Infliction of Emotional Distress and Punitive Damages

Count XIII of the Complaint alleges intentional infliction of emotional distress against all defendants, including Essex. In Pennsylvania, defendant's conduct must be "so outrageous in character and so extreme in degree as to go beyond all possible grounds of decency, and to be regarded as atrocious and utterly intolerable in a civilized society" in order to recover for intentional infliction of emotional distress. *Hoy v. Angelone*, 720 A.2d 745, 754 (Pa. 1988) (*quoting Buczek v. First National Bank of Mifflintown*, 531 A.2d 1122, 1125 (Pa. Super. 1987). "[It is not] enough that the defendant has acted with intent which is tortious or even criminal, or that he has intended to inflict emotional distress, or even that his conduct has been characterized by malice, or a degree of aggravation that would entitle the plaintiff to punitive damages for another tort." *Id*. (*citing Daughen*

v. Fox, 539 A.2d 858, 861 (Pa. Super. 1988) (internal quotation marks omitted) (other citation omitted)).

Plaintiff cites *Brownstein v. Gieda*, 649 F.Supp.2d 368 (M.D. Pa. 2009) (Munley, J.) to support her position. *Brownstein* held that conduct can be so egregious as to not require a special showing that the defendant knew his or her actions would cause emotional distress. *Id*. at 374. Plaintiff has pled facts which, although general in nature like in *Brownstein*, allege that the actions of Essex were "atrocious" and "utterly intolerable." The Court adopts and incorporates by reference its analysis at doc. no. 43, 12, and holds that plaintiff has stated a claim for intentional infliction of emotional distress and punitive damages against Essex.

V. Conclusion

For the foregoing reasons, defendant's Motion to Dismiss (doc. no. 29) will be DENIED. An appropriate Order follows.

s/Arthur J. Schwab
Arthur J. Schwab
United States District Judge

cc: All Registered ECF Counsel and Parties